REMARKS

STATUS OF THE CLAIMS.

Claims 45-70 and 74-76 are pending with entry of this amendment. Claims 45-67 are allowed. Claim 68 is amended herein. These amendments introduce no new matter.

35 U.S.C. §102.

Claims 68, 69, 74, and 75 were rejected under 35 U.S.C. § 102 as allegedly anticipated by Lavialle et al. (Anticancer Research (1989) 9:1265-1280). Office Action, page 1. This rejection is respectfully traversed.

Of the rejected claims, only claim 68 is independent. Claim 68 relates to a method for detecting a copy number variation in a suspected breast cancer sample by detecting an amplification of unique sequences from position q22 to position q24 on chromosome 17. Detection is carried out by hybridizing a suitable probe to the sample and detecting the hybridization complex.

In explaining the rejection, the Examiner stated:

> Lavialle teaches [a] method for detecting a copy number variation in a suspected breast cancer sample (see page 1267, figure 1, page 1266, column 2 and page 1269, column 1, line 5) on chromosome 17, from position q22 to position q24 (page 1269, column 1, lines 3-6, where Lavialle states "However, in this case, cells without DMs still have a high level of c-myc amplification (30 fold) and the c-myc copies are integrated into an ABR at 17q24."

Office Action, page 2. Thus, Lavialle teaches an amplification of c-myc sequences. C-myc sequences are from 8q24. Applicants' specification, page 34, line 10. In Lavialle's cells, amplified c-myc sequences were translocated from 8q24 to 17q24. Lavialle teaches nothing with respect to the sequences normally present at 17q24. Therefore, Lavialle fails to teach or suggest that an amplification of unique sequences from position q22 to position q24 on chromosome 17 is associated with anything, much less a breast cancer sample.

By contrast, Applicants demonstrated that the amplification detected at 17q22-q24 was an amplification of sequences normally present in this region. More specifically, Applicants' specification describes an fluorescence in situ hybridization (FISH) study using a probe specific for the 17q22-q24 region, which confirmed that the amplification observed was of sequences from this

region. Applicants' specification, page 89, line 19 - page 90, line 2. Thus, Applicants' specification, and not Lavialle, teaches that an amplification of unique sequences from position q22 to position q24 on chromosome 17 is associated with breast cancer. While Lavialle might arguably suggest detecting an amplification of 8q24 (c-myc) sequences in a suspected breast cancer sample, nothing in Lavialle teaches or suggests detecting an amplification of 17q22-24 sequences in such a sample.

Claims 69, 74, and 75 depend from claim 68 and are therefore novel over Lavialle for at least the same reason. Withdrawal of the § 102 rejection of claims 68, 69, 74, and 75 is therefore respectfully requested.

35 U.S.C. §103(A).

Claims 70 and 76 were rejected under 35 U.S.C. § 103(a) as allegedly obvious in light of Lavialle in view of Mullis *et al.* (U.S. Patent No. 4,683,202) Office Action, page 3. This rejection is respectfully traversed.

Claims 70 and 76 depend from claim 68 and therefore incorporate the element of detecting an amplification from 17q22 to 17q24. The Examiner contended that Lavialle teaches the detection of amplifications ***in*** this region. However, as explained above, Lavialle fails to teach or suggest the detection of amplifications ***from*** this region.

Mullis does nothing to remedy this deficiency. Mullis is cited as teaching the elements recited in claims 70 and 76, namely labeling the sample nucleic acid (claim 70) and using cDNA as the sample nucleic acid (claim 76). *See* Office Action, page 5. Mullis neither teaches nor suggests anything about detecting a copy number variation in a suspected breast cancer sample by detecting an amplification of unique sequences from "chromosome 17, position q22 to position q24," as recited in claim 68 and incorporated into dependent claims 70 and 76. Thus, the Lavialle-Mullis combination fails to teach or suggest all of the elements of rejected claims 70 and 76. Withdrawal of the § 103 rejection of these claims over Lavialle and Mullis is therefore respectfully requested.

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner form the intention to maintain the rejections, Applicants request a telephone interview with the Examiner prior to the issuance of another Office Action.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3509.

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